REMARKS

Reconsideration of the application is respectfully requested.

I. Telephone Interview

Applicants thank Examiner Hagopian for all of the courtesies extended during a telephone interview with Applicants representative on June 13, 2007. During the call Examiner Hagopian clarified and corrected her 35 U.S.C. §102(b) listed as item 4 in the currently outstanding Office Action. The rejection should be applied to claims 1, 3, 7-11, 13-16, 31, 33, 37-41, 43-49, 53-57, 59-63, 67-71 and 73-76. Clarification and correction was also given regarding item 8 in the currently outstanding Office Action. The 35 U.S.C. 102(b) rejection in view of Ohta has been withdrawn for claims 8-17, 19, 23-27, 29 and 30.

II. Claim Status

Claims 1, 3-27, 19-31, 33-47, 49-61 and 63-76 are currently pending. All claims have been rejected. Claims 1, 3-16, 28, 31-47, 49-61 and 63-76 have been cancelled without prejudice or disclaimer. Claims 77-79 are new claims.

After entry of this amendment claims 17, 19-27, 29, 30 and 77-79 will be pending.

Claims 17, 24 and 29-30 have been amended and no new matter has been added.

Claim 17 has been amended to add "the ratio of the fine granules by weight to the total weight of the tablet is 1 to 50%." Support for this amendment comes from the specification as filed at page 14, lines 2-10 and page 27, lines 2-6.

Claim 24 has been amended to correct grammar.

Claims 29 and 30 have been amended to add "ratio" and "by weight to the total weight." Support for this amendment comes from the specification as filed at page 14 lines 2-7 and page 14 lines 8-10.

New claims 77-79 find support in the specification as filed at page 12 lines 20-25 page 13 line 1 and page 25 lines 11-13. No new matter has been added.

II Claim Rejections

a) 35 U.S.C. §102(b) Rejection in View of Yoshinari.

Claims 1, 3-7, 9-10, 14, 15, 31, 33-37, 39-40, 45, 47, 49-53, 55, 56, 61, 63-67, 69, 70 and 75 stand rejected under 35 U.S.C. § 102(b) in view of Yoshinari (US 2001/0001105A1). Without conceding the correctness of the Examiners position, claims 1, 3-7, 9, 10, 14, 15, 31, 33-37, 39, 40, 45, 47, 49-53, 55-56, 61, 63-67, 69, 70 and 75 have been canceled without prejudice or disclaimer. Claim 32 was canceled in a previous amendment. Withdrawal of this rejection is respectfully requested.

b) 35 U.S.C. §102(b) Rejection in View of Ohta.

As a result of a telephone interview held with the Examiner claims 1, 3, 7-11, 13-16, 31, 33, 37-41, 43-49, 53-57, 59-63, 76-71 and 73-76 stand rejected under 35 U.S.C. §102(b) in view of Ohta (US 2001/0014340A1). Without conceding the correctness of the Examiners position claims 1, 3, 7-11, 13-16, 31, 33, 37-41, 43-49, 53-57, 59-63, 67-71 and 73-76 have been canceled without prejudice or disclaimer. Claim 48 was canceled in a previous amendment. Withdrawal of this rejection is respectfully requested.

c) 35 U.S.C. §112 First Paragraph

Claim 3 stands rejected under 35 U.S.C. §112, First Paragraph as containing new matter. Without conceding the correctness of the Examiner's position, claim 3 has been canceled without prejudice or disclaimer.

Claims 12-14, 28-30, 40-44, 58-60 and 72-74 stand rejected under 35 U.S.C. §112 First Paragraph as containing new matter. Without conceding the correctness of the Examiner's position Claims 12-14, 2, 40-44, 58-60 and 72-74 have been canceled without prejudice or disclaimer. Claims 29 and 30 are at issue. The Examiner asserts that there is no teaching that the fine granules, D-mannitol and disintegrator are present in the amounts and percentages claimed. The Examiner further states that it is unclear what is the claimed percentage of fine granules in terms of the entire composition. Applicants respectfully traverse.

Claims 29 and 30 have been amended to read wherein the ratio of the D-mannitol by weight to the total weight of the tablet is 20-99% and 0.5 to 30% respectively. Support is found within the specification as filed at page 14 lines 2-10 and page 27 lines 5-13. The specification teaches the limitations and therefore claims 29 and 30 raise no issues of new matter. Reconsideration and withdrawal is respectfully requested.

d) 35 U.S.C. §112 Second Paragraph

Claim 3 stands rejected under 35 U.S.C. §112, Second Paragraph as being indefinite. Without conceding the correctness of the Examiner's position claim 3 has been canceled without prejudice or disclaimer. Withdrawal of this rejection is respectfully requested.

e) 35 U.S.C. §103(a)

Claims 17, 19-23, 35 and 26 stand rejected under 35 U.S.C. §103(a) as obvious over Yoshinari (US 2001/000116A1) in view of the Examiner's statement of ordinary skill. The Examiner contends that while silent to the mixing of fine granules comprising an active agent, an absorbent, D-mannitol and a disintegrator it would have been obvious to modify the method steps of

Yoshinari because the selection of any order or performing process steps is *prima facie* obvious in the absence of unexpected results (citing MPEP 2144.04). Applicants respectfully traverse.

Amended claim 17 relates to an invention of "[a] process for producing an intraorally rapidly disintegrable tablet which comprises, granulating a mixture of a water-soluble pharmacologically active ingredient and an absorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminates to prepare fine granules, mixing the fine granules, D-mannitol and a disintegrator to prepare a material for compression molding, wherein the ratio of the fine granules by weight to the total weight of the tablet is 1 to 50% and subjecting the material to compression molding."

The amended claim 17 is characterized by the claimed features of (I) "granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminates" and (II) "mixing prepared fine granules, D-mannitol and a disintegrator to prepare a material for compression molding, wherein the ratio of the fine granules by weight to the total weight of the tablet is 1 to 50%." Combination of these two features (I) and (II) indeed gives tablets having excellent hardness (strength) and disintegration speed in the oral cavity.

The excellent effects of the claimed tablets of the invention, caused by combination of (I) and (II) are specifically described in Table 1 of the Specification. A method for preparing the tablet of Example 2 comprises steps (I) and (II). To the contrary, a method for preparing the tablet of Example 4 comprises step (I), but does not comprise step (II) and a method for preparing the tablet of Comparative Example 1 does not comprise steps (I) or (II). The method for preparing the tablet of Examples 2, 4 and Comparative Example 1 are the same adsorbent and the same tabletting method. The method for preparing the tablet of Comparative Example 1 is a similar method to that of the Examples in Yoshinari. It is apparent from the comparison of Example 2 with 4 in Table 1

that the tablet produced by the method comprising steps (I) and (II) is shown to have about twice the speed of disintegration. It is apparent from the comparison of Example 2 with Comparative Example 1 in the Table 1 that the tablet produced by the method comprising steps (I) and (II) is shown to have about eight times the speed of disintegration.

Yoshinari discloses "[a]n intraorally rapidly disintegrable tablet comprising a pharmacologically active ingredient and other some ingredients" and granulating a mixture of a pharmacologically active ingredient and other some ingredients" (Example 3), but does not disclose "granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent." The Examiner has stated that Yoshinari et al discloses calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium silicate aluminates", however, the aforementioned ingredients are disclosed as glidants or lubricants. Since glidants and lubricants are useless if not existing on surface of the fine particle, a person having ordinary skill in the art would not think of granulating a mixture of a water-soluble pharmacologically active ingredient and the aforementioned ingredients as the glidants or the lubricants. Yoshinari is silent regarding granulating a mixture of a water-soluble pharmacologically active ingredient and aforementioned ingredients in a tablet which give the beneficial effect of quick disintegration in the oral cavity.

Further, Yoshinari does not disclose "mixing prepared fine granules, D-mannitol and a disintegrator to prepare a material for compression molding," and "the ratio of the fine granules by weight to the total weight of the tablet is 1 to 50%" in the claimed invention are not disclosed in Yoshinari. Yoshinari is silent regarding the beneficial effect in the oral cavity which is obtained by the mixing prepared fine granules, D-mannitol and a disintegrator and by the specific ratio of the fine granules in the tablet.

Therefore, the inventions of the amended claim 17 and its dependant claims are not obvious over Yoshinari. Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 17, 19, 23-27, 29 and 30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ohta (US 2001/0014340). The Examiner contends that while Ohta is silent to the particular step of mixing fine granules comprising an active agent, an absorbent, D-mannitol and a disintegrator it would have been obvious to modify the method steps of Ohta because the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (citing MPEP 2144.04). Applicants respectfully traverse.

Applicants ask the Examiner to consider the previous arguments made to overcome the obviousness rejection made in view of Yoshinari and the following: Ohta discloses "[a]n intraorally rapidly disintegrable tablet comprising a pharmacologically active ingredient and light anhydrous silicic acid," but only discloses that the aforementioned ingredients are disclosed as lubricants and does not disclose (I) "granulated a mixture of a water-soluble pharmacologically active ingredient and an adsorbent." Further, Ohta does not disclose "mixing prepared fine granules, D-mannitol and a disintegrator to prepare a material for compression molding," and "the ratio of the fine granules by weight to the total weight of the table is 1 to 50%" as in the claims. The method for preparing the tablet of the Examples in Ohta is similar the method of Comparative Example 1 in the Specification. Ohta is silent about the granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent nor does Ohta disclose the ratio of the fine granules in the tablet which give the beneficial effect of quick disintegration in the oral cavity. Therefore, the inventions of the amended claim 17 and its dependant claims are not obvious over Ohta. Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the above amendments and remarks applicants believe the pending application is in condition for allowance. Such action is earnestly solicited. If there are any remaining issues the Examiner is invited to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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